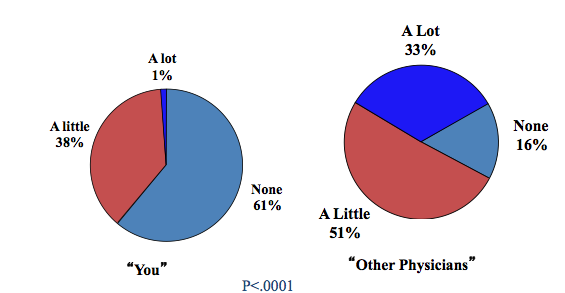
INTRO TO EBM

OBJECTIVES

* Identify factors that inform clinical decision making
  + Valid Bases
    - Scientific data
    - Experience
    - Training
  + Other influences (NOT VALID BASIS)
    - Reimbursement
    - Allure of new technology
    - Current opinion
    - Bias
  + Conflicts of interest
    - Perceived influence of pharmaceutical reps on prescribing practices “Not Me!”
    - 
  + Intellectual Goals of Medical Education
    - To train and test habits of thought, rather than to collect and store a set of facts, as squirrels hoard the nuts on which they hibernate. You should never be satisfied with an accumulation of information; a considerably more profound facility is the ability to relate the subject to the whole
    - To develop in you a thoughtful and critical attitude by which you may continue to be a scholar of medicine after you have ceased being a medical student
* Define Evidenced-Based Medicine
  + EBM de-emphasizes intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research
  + The conscientious, explicit, and judicious use of current best evidence in making decision about the care of individual patients. It means integrating individual clinical experience with the best available clinical evidence from systematic research
  + Clinical Experience and Expertise VS. Research evidence
    - Clinical Experience and Expertise
      * Proficiency and judgment acquired through clinical experience and clinical practice
      * This is reflected in more effective and efficient diagnosis and more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care
    - Research Evidence
      * Both basic science and patient -centered clinical research into the accuracy and precision of prevention strategies, screening tests, diagnostic tests (including the clinical examination, and efficacy and safety of therapy, and prognosis
      * Research evidence evaluates previously accepted strategies and paradigms and may replace them with new ones that are more accurate, more efficacious, and safer
    - Expertise and Evidence
      * Neither alone is sufficient in the practice of medicine
      * Without clinical expertise, even excellent external evidence may be inapplicable to or inappropriate for and individual patient
      * Without current best evidence, practice risks becoming rapidly out of date, to the detriment of the patient
    - Paradigm Shift-1
      * Past: Unsystematic observations from clinical experience build one’s knowledge and form the best basis for treating individual patients.
      * Current: Clinical experience and clinical instincts are crucial and necessary but not sufficient
    - Paradigm Shift-2
      * Past: The study of basic mechanisms of disease and pathophysiologic principles is a sufficient guide for clinical practice.
      * Current: The rationale (s) for diagnosis and treatment which seem to follow from basic pathophysiologic principles may be incorrect.  – Example: Chemotherapy kills cancer, because these cells are growing more rapidly than normal cells.
    - Paradigm Shift-3
      * Past: Content expertise and clinical experience are a sufficient base to generate valid guidelines for clinical practice.
      * Current:
        + Understanding rules of evidence is necessary to correctly interpret literature on causation, prognosis, diagnostic tests and treatment strategy.
        + Only then can physician use knowledge base and clinical acumen to provide the best scientific and humanistic care for individual patients.
  + Skills Required for EBM
    - Understanding basics of statistical methods
    - Knowing and using both primary and secondary sources of valid information
    - Efficient literature searching
    - Application of formal rules of evidence in evaluating the clinical literature
      * Critical thinking and appraisal
    - Ability to relate the evidence from literature to the individual patient
  + Life Long Learning Model
    - EBM is process of lifelong, self-directed, problem based learning
    - EBM is patient centered and focused on information about prevention, screening, diagnosis, prognosis and therapy
    - EBM targets reading to issues related to specific patient problems no reviewing all the literature for interesting articles
  + WHY EBM?
    - Before Google, UpToDate and Epocrates…
      * Physicians self reported 2 questions arising for every 3 patients seen
      * On observation, physicians generated 5 questions for each patient seen
      * Use of “evidence cart” on rounds. 71 searches to answer clinical questions. 52% confirmed the decision, 25% lead to a new therapy, 23% corrected the previous plan
* Identify parts of a well-built clinical question
  + 6-step EBM Process
    - 1. The patient—start with the patient- a clinical problem or question arises out of care of the patient
    - 2. The question- Construct a well built clinical question (or set of questions) derived from the case
      * Types of Questions
        + Diagnosis: How to select and interpret diagnostic tests
        + Therapy: How to select treatments that do more good than harm and are worth the efforts and costs of doing them
        + Prognosis: How to estimate a patients clinical course over time and anticipate likely complications
        + Harm/Etiology: How to identify causes of disease (including iatrogenic forms)
        + Cost/Benefit: How much does the individual (or society) get for the financial expenditure or physical/emotional toll
    - 3. The resource- Select the appropriate resources and conduct a search
      * Types of Studies
        + Case Series/Case Reports

Consists of collections of reports on the treatment of individual patients or a report on a single patient

Because they are reports there is no use of control groups they have no statistical validity

Ex: 3 interesting patients w/ lung cancer before age 50 who have no personal smoking history but worked as a bartender

* + - * + Case Control

Subjects, often patients, who already have a certain condition are compared with people who do not. They often rely on patients records or recall for data

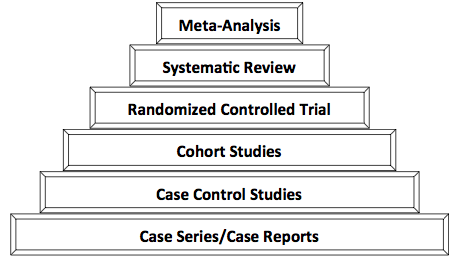
Often less reliable than randomized controlled trials and cohort studies because showing a statistical relationship does not mean that one factor necessarily caused the other

Ex: study of patients w/ lung cancer compared to those without lung cancer to determine whether occupational second hand smoke increased risk.

* + - * Longitudinal observational studies
        + follow patients who have a specific exposure or condition or receive a particular treatment over time and compare them (and their outcome) with another group that has not been affected by the exposure, condition or treatment being studied.
      * Cohort studies
        + are not as reliable as randomized controlled studies, since the two groups may differ in ways other than in the variable under study.
        + Example: Study of bartenders (exposed to second hand cigarette smoke) compared with age matched Mormon entrepreneurs and follow disease outcomes.
      * Randomized Controlled Clinical Trials
        + These are carefully planned projects that study the effect of a intervention on real patients. They include methodologies that reduce the potential for bias (randomization and blinding) and that allow for comparison between intervention groups and control groups (no intervention)
        + Commonly used in studies of the efficacy of drugs and devices
        + Can not be used for most life-style exposures, such as smoking, diet or sexual practices
      * Often a “double blind” if involves a therapy
        + Study designed to show the efficacy of a diagnostic test or treatment using best-known comparator.
        + This is a controlled trial that looks at subjects (patients) with varying degrees of an illness or condition and administers standard and investigational diagnostic test or treatment to all of the individuals in the study group.
        + Examples:

Survival benefit of MRI scanning vs. mammography in detecting early (curable) breast cancer in subjects with BRCA family history;

Efficacy of h. zoster vaccine in preventing shingles in subjects age 60 to 80.

* + - * Systematic Review
        + Reviews of the literature that are focused on a clinical topic to answer a specific question.
        + An extensive literature review is conducted to identify all studies with sound methodology.
        + The studies are reviewed, assessed, and the results are summarized according to the predetermined criteria of the review question.
      * Meta-analysis
        + A study that thoroughly examines a number of valid studies on a topic and combine the results using accepted statistical methodology as if they were from one large study.
        + Part of the methodology includes critical appraisal of the selected randomized controlled trials selected for analysis.
      * Evidence Pyramid
        + 
      * Select the appropriate resource(s) and conduct a search
        + Mulford Library Website:

<http://www.utoledo.edu/library/mulford/index.html>

<http://libguides.utoledo.edu/ebp>

Link to PubMed

Additional Resources for Evidenced Based Practice such as ACP Journal Club, the Cochrane Library

Tutorials/Help Sheets for PubMed Searches

* + - 4. The evaluation- Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in clinical practice)
      * This is a critical cognitive step, as we must appraise the evidence (of a study or studies) for validity (closeness to the truth), reliability and applicability to the question and the patient
        + Are the results of the study valid?
        + What are the results?
        + Will the results help in caring for my patient?
      * Validity= Are you measuring what you think you are measuring?
        + the purpose of a screening test is to correctly identify individuals who do and do not have pre-clinical disease. Those who have pre-clinical disease should test positive.
        + Those who do not have pre-clinical disease should test negative.
        + Validity Factors

Study may be properly conducted (internally valid) but not be generalizable (externally valid)

External: A research study or experiment has external validity if the results obtained would apply to other similar programs or approaches. Can we generalize with confidence that this is true for the target population?

Because you are often using a restricted artificial population for your own study, it may be hard to generalize to everyone.

Generalizability may also be affected by those who volunteer for a study, as in they may be inherently different from those who do not volunteer (participation bias).

Lack of external validity, affected by

Participation rates,

Selection of population

Lack of Internal validity

Non-compliance: not taking medication or treatment

Drop-outs or attrition

Drop-ins (contamination)

Drop-ins may be when someone from the placebo group decides to change to one of the treatment groups without anyone knowing, thus causing problems with the results.

* + - * + Validity criteria should be applied before an extensive analysis of the study data (results or conclusions)

Methodology, including potential bias, randomization, blinding, accounting for all patients

* + - * + Because all answers to validity questions may not be clearly stated, clinicians will need to make their own judgments
      * Reliability = Can you get the same results over repeated measurements?
      * Generalizability = How well do the results of the study apply to a larger population of subjects (external validity)
      * Evaluation Criteria
        + Assignment Randomized
        + All subjects accounted for at end of trial – adequacy of follow-up
        + Were patients, clinicians, other study personnel blinded to treatment allocation
        + Were groups similar at beginning of trial – baseline characteristics
        + Aside from intervention, were all groups treated equally
        + Sufficient number to subjects to give study power to detect difference in outcome
        + Intention to treat analysis
    - 5. The patient- Return to the patient. Integrate that evidence with clinical expertise, patient preferences and apply it to practice
      * return to the patient to determine applicability
      * Treatment effect
        + Relative Risk (RR) = Y/X= 0.64/0.67 = 0.96
        + RR Reduction (RRR) = (1- Y/X) x 100 = (1-0.96) x 100 = 4%
        + Absolute Risk Reduction (ARR) = (X – Y) x 100 = (0.67-0.64) x 100=3%
        + Number Needed to Treat (NNT) to prevent one adverse outcome =

1/(X - Y) = 1/0.03 = 33 patients.

(3 out of each hundred patients benefit)

* + - * + Y = 0.64 = Risk in treated; X = 0.67 = Risk in controls
        + If Y = 0.30 and X = 0.33
        + RR = .30/.35 = .91
        + RRR = 100 - 91 = 9 %
        + But ARR = 3x 100= 3%
        + Do you tell your patient there is a 9% risk reduction or a 3% risk reduction?

1 of 33 or 1 of 11 benefit?

NNT = 1/0.03 = 33

* + - * Integrate the evidence with
        + Clinical expertise

Other clinical social factors

* + - * + Patient preferences
      * Apply to practice
      * Applicability
        + Article meets criteria of validity
        + Population similar enough to consider results applicable in her case (external validity)

Any qualifiers?

* + - * + Patient needs to know

Benefit - 1-33 patients will avoid hospital if on digoxin

Risks - frequent blood draws, low risk of toxicity, cost of drug (low)

* + - 6. Self-evaluation- evaluate your performance with the patient
      * Did the process tell me what I needed to know to help the patient?
      * What might I have done differently?
      * Were there other sources I should have used?
      * Did I take enough of the patient’s characteristics (physical, social, psychological, financial, ethnic) into consideration?
      * Did the patient feel helped by what was done?
      * Did it make a difference in what the patient decided to do?
  + A good Clinical Question
    - Patient or problem
      * How would you describe a group of patients similar to yours? This may include primary problem, disease, co-morbidities, sex, age, race
    - Intervention, prognostic factor, or exposure
      * What do you want to do for the patient? Meds? Tests? Surgery? What factors may influence the prognosis? Age? Co-morbidities? What was the patient exposed to? Tobacco? Asbestos?
    - Comparison
      * What is the main alternative to compare with the intervention? Are you trying to decide between two drugs, a drug and no meds, or two diagnostic tests? The clinical question does not always need a specific comparison
    - Outcomes
      * What do you wish to accomplish, measure, improve or affect? What are you trying to do for the patient? Relieve symptoms? Reduce adverse events? Improve function or scores?
* Identify EBM searching strategies that could improve retrieval
  + This is covered more in the next Lecture.
* Identify key issues that help determine the validity of results of a study (pasted from above)
  + Validity= Are you measuring what you think you are measuring?
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